

510(k) Summary of Safety and Effectiveness
Afghan External Fixator

Submitted By: Smith & Nephew, Inc.,
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116
DEC 10 2009

Date: July 1, 2009

Contact Person: Laura Sejnowski, Regulatory Affairs Specialist
Tel: (901) 399-5349 Fax: (901) 398-5146

Proprietary Name: **Afghan External Fixator**

Common Name: External Fixation System

Classification Name and Reference: 21 CFR 888.3030, smooth or threaded metallic bone fixation fastener, Class II

Device Classification for Predicate Devices: 21 CFR 888.3030, smooth or threaded metallic bone fixation fastener, Class II

Device Product Code and Panel Code: Panel: Orthopedics / 87
Product Code: KTT

Device Description:

Subject of this premarket notification is the Afghan External Fixator. The Afghan External Fixator is a unilateral external fixation system that offers specially designed components used in the management of small bone fractures. System components include male and female struts (*or frame*) and nuts made from stainless steel material. Like the predicate devices listed below, the subject components are used in conjunction with Kirschner wires to provide a device customized to meet specific patient needs.

Intended Use:

The Afghan External Fixator and its components are intended to be used in adolescents (12-21 years) and adults for securing small bone fractures and bone fragments on non-long bones including: patella and olecranon.

Technological Characteristics:

The **Afghan External Fixator** is similar to legally marketed devices listed below in that they share similar indications for use, are manufactured from similar materials, and incorporate similar technological characteristics.

Substantial Equivalence Information:

When compared to the predicate devices listed below, substantial equivalence is based on similarities in design features and overall indications for use.

- Osteo Kirschner Wires – K971962
- Smith & Nephew Kirschner Wires – Preamendment
- Smith & Nephew External Fixation System – *Unilateral (Linear) & Multilateral (Circular) Fixators and Accessories* – K994143



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center -- WO66-0609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
c/o Ms. Laura Sejnowski
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

DEC 10 2009

Re: K092002
Trade/Device Name: Afghan External Fixator
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: December 3, 2009
Received: December 4, 2009

Dear Ms. Sejnowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Page 2 – Ms. Laura Sejnowski

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K092002

Device Name: Afghan External Fixator

Indications for Use:

The Afghan External Fixator and its components are intended to be used in adolescents (12-21 years) and adults for securing small bone fractures and bone fragments on non-long bones including: patella and olecranon.

Components in the Afghan External Fixator are for single use only.


Prescription Use X
(Part 21 CFR 801.109)

AND/OR

Over-the-Counter Use _____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092002